SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5741–5780

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient including the quantity and kind of alcohol; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (l), the article was, or purported to be, or was represented as, a drug composed wholly or partly of tetracycline, a derivative of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503(b)(1), the article was dispensed without a prescription from a practitioner licensed by law to administer the article; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5741. Achromycin capsules. (F.D.C. No. 42171. S. No. 4–823 P.)

QUANTITY: 2 btls. containing a total of 419 *Achromycin capsules* at Greenbelt, Md., in possession of State Drugs, Inc. (Greenbelt Pharmacy).

SHIPPED: The capsules were manufactured in the State of New York, and delivered to the dealer at Greenbelt, Md., by an unknown person, sometime prior to 6–24–58.

LABEL IN PART: (Btl.) "Greenbelt Pharmacy * * * 131 Centerway Greenbelt, Md. No. —— Dr. —— Achromycin 'V'."

RESULTS OF INVESTIGATION: The article was in the form of physicians' samples when delivered to the dealer, and after such delivery the article was repackaged into the above-mentioned bottles.

Analysis showed that the article contained approximately 250 milligrams of tetracycline per capsule.

LIBELED: 9–4–58, Dist. Md.

CHARGE: 502(b)(2)—the label of the article, while held for sale, failed to bear an accurate statement of the quantity of contents; 502(e)(2)—the label of